

REMARKS

Initially, Applicants thank the Examiner for conducting a telephonic interview with Applicants' representatives Sean Ryder and Steve Roylance on December 23, 2003. During the interview, the current rejections of record, the patentability of the claims and possible amendments to the claims to overcome the rejections of record were discussed. The Examiner asserted that it was necessary to include information regarding the phenotype in the claims to enable one of ordinary skill in the art to use the invention. Applicants noted that the art cited by the Examiner states that such gene-mutated animals having a mutant presenilin-1 gene have no overt phenotype. The Examiner asserted that some physical characteristic was required to enable use of the claimed invention. The Examiner also noted that amending the claim to gene-mutated mouse would help to overcome the written description rejection.

Applicants thank the Examiner for withdrawing the rejections of claims under 35 U.S.C. § 102, 103 and 112, second paragraph.

Reconsideration and withdrawal of the rejections of record in view of the foregoing amendment and the following remarks is respectfully requested.

Summary of Status of Amendments and Office Action

In the present amendment, claims 1, 3-11, 13, 16-18, 36, 46, 48 and 51 are amended and claims 12, 14-15 and 47 are canceled. Therefore, claims 1-11, 13, 16-51 are pending with claims 1, 3-6, 10, 18-22, 24, 25, 27, 29, 34, 43 and 51 being independent.

In the Office Action, new claim 51 was entered.

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In the Office Action, the Restriction Requirement of July 22, 2002 was again deemed proper and made final.

In the Office Action, claims 1-2, 5-9, 12-17, 33 and 36-42 and 51 are rejected and claims 3-4, 10-11, 18-32, 34-35 and 43-50 were removed from consideration.

Claims 1, 2, 5-9, 12-17, 33, 36-42 and 51 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 5-9, 12-17, 33, 36-42 and 51 are rejected under 35 U.S.C. § 112, first paragraph as nonenabled.

Explanation and Support for Amendments

Applicant submits that each of the foregoing amendments is fully supported by the specification at pages 11-19.

Disclosure Statement

Applicants request that the Examiner include an initialed copy of the Form PTO-1449, accompanying the Supplemental Information Disclosure Statement filed May 29, 2003, with the next communication from the U.S. Patent and Trademark Office.

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Response to Restriction Requirement

Applicants note that the Examiner has made the Restriction Requirement final. However, Applicants again submit that the restriction requirement is in error and should be withdrawn. Specifically, Applicants note that there is a significant amount of overlap in the Groups set forth by the Examiner. There should be no undue burden for the Examiner to examine each of the groups of invention. Therefore, the restriction should be withdrawn.

Applicants note that withdrawn claims 3-4, 10-11, 18 and 46 have been presently amended to place them in condition for allowance should the Examiner withdraw the restriction requirement or rejoin claims.

Applicants further note that, if product claims are found to be patentable, the withdrawn process claims which include the recitations of the product claims should be rejoined. The Examiner is reminded that M.P.E.P. § 821.04 states:

However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined.

Thus, at the minimum, claims 34-35 drawn to a method of producing a gene-mutated mouse, plus any other claim the Examiner deems proper, should be rejoined upon allowance of a claim to a gene-mutated mouse.

Still further, Applicants remind the Examiner that if a generic claim is found to be allowable, the claims of the nonelected species should be examined if they depend from or otherwise include each of the limitations of the allowed generic claim. See M.P.E.P. § 809.02(c). Therefore, in the present case, if generic claim 1 is found to be allowable, Applicants submit that,

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at least claims 3-4, 18, 25-26, 29-33, 46 and 48-50, plus any other claim the Examiner deems proper, should be considered, rejoined and allowed.

Response to §112, First Paragraph Rejections

Claims 1, 2, 5-9, 12-17, 33, 36-42 and 51 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection again asserts that the claimed invention encompasses transgenic animals as well as knockout animals or non transgenic animals, and there is no description of the phenotype of any of these animals.

In response, Applicants note that the claims now explicitly state that the gene-mutated animal is a mouse. Support for this recitation is found throughout the specification, and particularly at page 5. Applicants amendment should not be construed as an acquiescence to the Examiner's rejection, but is merely made to speed prosecution and lead to the early allowance of a patent directed to the claimed invention. Applicants expressly reserve the right to pursue the original claims in a later related application.

Claims 1, 2, 5-9, 12-17, 33 and 36-42 are also rejected under 35 U.S.C. § 112, first paragraph as nonenabled. The rejection changes the basis from the prior Office Action from scope to full lack of enablement because the specification, while teaching the making of a transgenic mouse with a OS2 mutation, does not teach what are the phenotypes or characteristics of the mouse and therefore an artisan of skill would not know how to use the transgenic animal.

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Applicants respectfully disagree with the Examiner and again assert that Applicants' specification adequately discloses a method to enable one of ordinary skill in the art to create additional knockin non-human gene-mutated animals from those disclosed in the specification. However, to speed prosecution and lead to the early allowance of a patent directed to the claimed invention, Applicants have amended the independent claims to recite that the mutation of the presenilin-1 gene cause the physical characteristic of overexpression of Amyloid β 42 in the brain of the gene-mutated mouse. During the telephone interview, the Examiner intimated that such an amendment should lead to an allowable claim.

For these reasons, Applicants respectfully request that the Examiner withdraw the rejection of claims 1, 2, 5-9, 12-17, 33, 36-42 and 51 under 35 U.S.C. § 112, first paragraph.

CONCLUSION


Applicants submit that the foregoing arguments traverse the Examiner's objections and rejections.

Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested. For the reasons advanced above

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Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully Submitted,
Masatoshi TAKEDA et al.



Bruce H. Bernstein
Reg. No. 29,027

Reg No
48,905

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191